PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Tracee Eidenschink, John Peckham**
Application No.:	**10/728516**
Filed:	**December 5, 2003**
For:	**Detachable Segment Stent**
Examiner:	**Melanie Ruano Tyson**
Group Art Unit:	**3773**

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P.O. Box 1450
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Docket No.: S63.2B-11293-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified Application in which claims 1, 2, 4-14, 35-38 and 55-57 were rejected in the Final Office Action mailed November 17, 2009. A Notice of Appeal was filed in this case on January 7, 2010. This brief is submitted in accordance with 37 CFR. § 41.37. The fees required under 37 CFR § 41.20(b)(2), and any petition for an extension of time required for filing this brief, are addressed in the accompanying Transmittal Letter.

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(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of Claims

Claims 1, 2, 4-14, 35-38 and 55-57 stand rejected and are the subject of this appeal. Claims 3, 15-34 and 39-54 have been cancelled.

(iv) Status of Amendments

No claim amendments have been filed subsequent to the Final Office Action mailed November 17, 2009.

(v) Summary of Claimed Subject Matter

Independent claim 1 recites a stent comprising an expandable framework 26 and an electrical lead 80. See e.g. Figure 5, page 9, line 29 and page 10, lines 23-26. The expandable framework comprises a plurality of serpentine bands 12 including a first serpentine band and a second serpentine band. Each serpentine band comprises alternating peaks 14 and valleys 16 connected by band struts 18. See Figure 1, provided below, and page 5, line 30-page 6, line 4. Adjacent serpentine bands 12 are connected by connector struts, including permanent 20 connector struts and disengageble connector struts 28. See page 6, lines 6-7 and 13-14. The first serpentine band is connected to the second serpentine band by at least one permanent connector strut 20 extending from a valley 16 of the first serpentine band to a peak 14 of the second serpentine band. See Figure 1. Each remaining valley 16 of the first serpentine band is connected to a peak 14 of the second serpentine band by a disengagable connector strut 28. See Figure 1. The electrical lead 80 extends from said expandable framework and is electrically coupled to the disengagable connector struts 28 such that the disengagable connector struts 28 disengage by electrolytic detachment. See page 7, lines 12-15 and page 9, line 29-page 10, line 4.

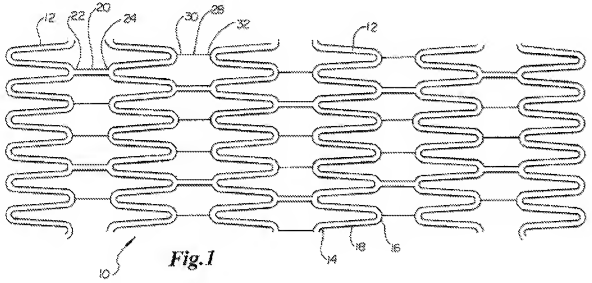


Fig.1

Dependent claim 4 depends from claim 1 and requires the electrical lead 80 to be attached directly to at least one disengagable connector strut 28. See e.g. Figure 5 and page 10, lines 12-14.

Dependent claim 5 depends from claim 1 and requires the electrical lead 80 to be attached directly to each of the disengagable connector struts 28. See e.g. Figure 5 and page 10, lines 12-14.

Dependent claim 6 depends from claim 1 and requires a second electrical lead, wherein each electrical lead 80 connects to at least one disengagable connector strut 28. See e.g. Figure 5 and page 10, lines 20-22.

Dependent claim 8 depends indirectly from claim 1 and requires the stent to self-expand to an intermediate deployment diameter, wherein the stent is restrained from further expansion by at least one disengagable connector strut 28. See page 7, lines 5-11.

Dependent claim 9 depends from claim 8 and requires the stent to self-expand to a full deployment diameter upon disengagement of the at least one disengagable connector strut 28. See page 7, lines 5-11.

Dependent claim 12 depends indirectly from claim 1 and requires at least one disengagable connector strut 28 to be connected to a serpentine band 12 at a necked portion 36. See Figure 4, provided below, and page 8, lines 23-26.

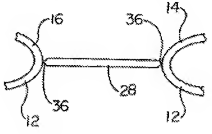


Fig.4

Independent claim 2 recites a stent for implantation in a living body comprising a first serpentine band 12 connected to a second serpentine band 12 by at least one permanent connector strut 20. The first serpentine band 12 is also connected to the second serpentine band 12 by at least one disengagable connector strut 28. See Figure 1 and page 6, lines 6-7 and 13-14. At least a portion of the at least one disengagable connector strut 28 is made from a material having a higher corrosion potential than a material used to form said serpentine bands 12. See page 8, lines 4-10 and page 9, lines 1-4.

Independent claim 35 recites a stent comprising a cylindrical metal framework 26 having a plurality of cells. See page 2, lines 13-14. The framework comprises a first serpentine band 12, a second serpentine band 12, at least one permanent connector strut 20 and a plurality of

disengageble connector struts 28. See Figure 1 and page 6, lines 6-7 and 13-14. Each serpentine band 12 comprises alternating peaks 14 and valleys 16 connected by band struts 18. See page 5, line 30-page 6, line 4. Each permanent connector strut 20 connects a valley 16 of the first serpentine band 12 to a peak 14 of the second serpentine band 12. The plurality of disengagable connector struts 28 connect the remaining valleys 16 of the first serpentine band 12 to the remaining peaks 14 of the second serpentine band 12. See Figure 1. Upon disengagement of the disengagable connector struts 28, the number of cells decreases and the mass of the metal in the metal framework decreases. See page 11, lines 12-19.

Dependent claim 37 depends indirectly from claim 35 and requires a portion of each cell to be defined by a portion of a permanent connector strut 20 after disengagement of said disengagable connector struts 28. See page 11, lines 20-24.

Dependent claim 57 depends from claim 35 and requires at least a portion of a disengagable connector strut 28 to be made from a material having a higher corrosion potential than a material used to form said at least one permanent connector strut 20. See page 8, lines 4-10 and page 9, lines 1-4.

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether the Examiner erred in rejecting claims 1, 2, 4-14, 35-38 and 55-57 under 35 USC § 103 over a combination of Mitsudou (US 7029492) in view of Acosta (US 7137993).

(vii) Argument

Issue 1: Whether the Examiner erred in rejecting claims 1, 2, 4-14, 35-38 and 55-57 under 35 USC § 103 over a combination of Mitsudou (US 7029492) in view of Acosta (US 7137993).

The Examiner erred in rejecting the pending claims because a person of ordinary skill in the art would not have been motivated to modify Mitsudou as asserted in the rejection. Further, even if the Mitsudou stent was modified as proposed by the Examiner, the resulting device would not meet each limitation of any rejected claim.

1. There is No Motivation to Make the Proposed Modification Because the Examiner's Asserted Motivation is Deficient and There is No Reasonable Expectation of Success

Mitsudou Reference

Mitsudou teaches a stent formed from a plurality of wavy annular members (e.g. 2b), which are connected by connection portions 4. See column 3, lines 48-53 and Figure 4 provided below.

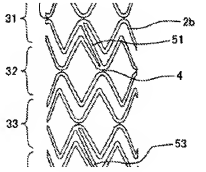


FIG. 4

Mitsudou teaches that some of the connection portions 4 located in the vicinity of the axial center of the stent are weakened, and can be broken by inserting an inflation balloon through the stent sidewall and inflating the balloon. See e.g. column 3, lines 53-61 and Figure 18, provided below.

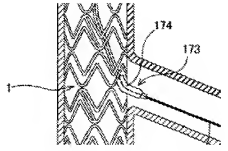


FIG. 18

As the balloon 174 is inflated, portions of the annular elements 2a, 2b in contact with the balloon 174 are dilated and the weak connector 4 oriented over the branch vessel is broken. This creates an enlarged side branch opening, which allows flow into the branch vessel. See column 13, lines 12-14, column 26, lines 26-51 and Figures 22 and 23, provided below.

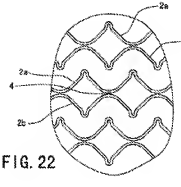


FIG. 22

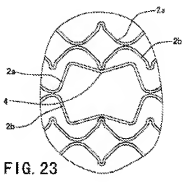


FIG. 23

Thus, Mitsudou teaches a balloon expandable stent having several weakened connectors, wherein a balloon can be positioned through the stent sidewall and used to dilate a side branch opening by breaking a weakened connector and forcing annular elements 2a and 2b apart.

Acosta Reference

Acosta teaches a stent delivery system having multiple stents 122 that are delivered in series. In some embodiments, the stents 122 are attached to one another by frangible coupling elements 124. As the stents 122 are delivered to a delivery site, the frangible coupling elements 124 are broken to separate the individual stents 122. See e.g. Abstract, column 14, lines 29-32 and Figure 9A, provided below. Figure 9A illustrates a mechanical shearing element 132 for breaking the frangible coupling elements 124. See column 14, line 39.

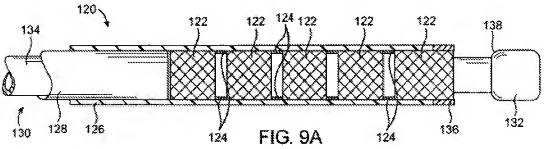


FIG. 9A

Acosta states, "For the delivery of individual prostheses or stents which are joined by frangible or breakable links, as discussed above, it will often be desirable to provide a shearing mechanism on the catheter. The shearing mechanism will usually be mechanical, but could also be electrolytic, ultrasonic, or chemical." See column 6, lines 18-23.

The Asserted Motivation for the Proposed Modification is Deficient

The Examiner alleges that the subject matter of the pending claims is obvious, and proposes to modify Mitsudou using teachings from Acosta. See Final Office Action at page 3.

The Examiner does not discuss the proposed modification(s) to Mitsudou in detail. The Examiner merely provides the following assertion at page 3

> Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Acosta to Mitsudou's device would have yielded predicable results and resulted in an improved system, namely, a system that would enable disengagement of the disengagable connectors at desired locations directly with electrical leads, thus eliminating the step of having to introduce a balloon into desired portions of the stent after the stent has been deployed.

Although the rejection asserts an alleged reason for the modification, the Examiner has not identified a reason that would have actually prompted a person of ordinary skill in the art to modify Mitsudou as proposed in the rejection. The modification was proposed in a hindsight attempt to reach the subject matter of the pending claims. Contrary to the Examiner's assertion, the proposed modification would not "eliminat[e] the step of having to introduce a balloon into

desired portions of the stent after the stent has been deployed" because a balloon would still be required to dilate a side opening as originally taught by Mitsudou.

A rejection under 35 USC § 103 must identify a reason that would have prompted a person of ordinary skill in the art to combine elements in the way of the claimed invention. See *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

During the Mitsudou dilatation process, a weak connector is broken by balloon-based mechanical forces. See column 13, lines 12-14, column 26, lines 26-51. Thus, the concept of breaking the weak connector results as a byproduct of the desire to dilate a side branch opening, which stems from a desire "[t]o secure favorable blood stream to the branched blood vessel." See column 26, lines 26-30.

The rejection proposes to substitute electrolytic detachment of a weak connector for a side branch dilatation step that is accomplished by balloon; however, the electrolytic detachment is not a suitable alternative for balloon dilatation because it does not accomplish dilatation. Even if a weak connector 4 could be broken electrolytically, disengagement of the weak connector 4 alone would not enlarge a side branch opening. After the electrolytic detachment, the stent would retain the same annular band 2a, 2b configuration as before the electrolytic detachment – see e.g. Mitsudou Figures 22 and 23 below, along with an excerpt from Figure 22 (center image) that has been modified to show the Examiner's proposed stent after electrolytic detachment of a weak connector 4. In order to dilate the side branch opening to the configuration illustrated in Figure 23, a balloon must still be used to dilate the annular bands 2a, 2b, even if the weak connector 4 was previously broken electrolytically.

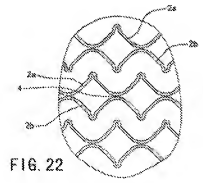
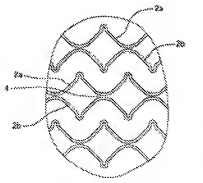


FIG. 22

Mitsudou before dilation.



Examiner's proposed stent after electrolytic detachment

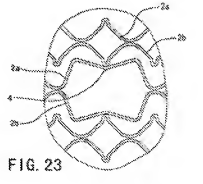


FIG. 23

Mitsudou after balloon dilation.

Thus, the modification proposed by the Examiner would not eliminate the balloon

expansion step, as asserted in the rejection. The modification would add cost and manufacturing complexity to the Mitsudou device without adding any useful benefit. Absent the desire to enlarge a side branch opening, there is no reason to break a weak connector 4 in the Mitsudou stent, and electrolytic detachment alone will not enlarge a side branch opening. Therefore, a person of ordinary skill in the art would not have been motivated to modify Mitsudou to provide for electrolytic detachment of a weak connector as proposed by the Examiner, and the Examiner has not presented a *prima facie* case of obviousness against the rejected claims.

There is no Reasonable Expectation of Success

The Examiner asserts that modifying Mitsudou to have electrolytic disengagement is merely a substitution of a known alternative to Mitsudou's mechanical disengagement technique; however, neither Mitsudou nor Acosta teach that electrolytic disengagement is a blanket substitute for balloon-based mechanical disengagement.

Mitsudou does not disclose or suggest electrolytic detachment.

The totality of Acosta's teachings with respect to electrolytic detachment are the following two sentences: 1) "The shearing mechanism will usually be mechanical, but could also be electrolytic, ultrasonic, or chemical;" and 2) "In other cases, the shearing mechanism could be an electrode for inducing electrolytic breakage of the link, an ultrasonic transducer for mechanically degrading a susceptible link (i.e. a link having a resonant frequency which corresponds to the ultrasonic transducer), a luminal port for releasing a chemical agent selected to chemically degrade the link, or the like." See column 6 at lines 21-23 and 34-40.

Although Acosta teaches that mechanical disengagement techniques or electrolytic disengagement techniques can be used in the Acosta device, there is no teaching that electrolytic disengagement is a substitute for balloon-based mechanical disengagement. For example, there is no disclosure in Acosta that a frangible link configured for mechanical disengagement would be capable of electrolytic disengagement merely by attaching an electrode to it.

Mitsudou does not disclose or suggest that the weak connectors are capable of being electrolytically detached. Thus, even if an electrode were attached to the Mitsudou stent, the Examiner has not provided any evidence that the Mitsudou weak connectors would actually be capable of detaching electrolytically. Thus, the Examiner has filed to show that the proposed

modification has a reasonable expectation of success.

The prior art can only be combined to reject claims as *prima facie* obvious when there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Examiner has not established a reasonable expectation of success. Therefore, the rejection has not established a *prima facie* case of obviousness against the rejected claims.

2. Impermissible Hindsight and Additional Issues with Modification

As discussed above, Mitsudou teaches breaking a selected weak connector for the purpose of dilating a side branch opening. Some of the pending claims, however, require multiple disengageble connector struts to detach electrolytically.

From the Examiner's statement of rejection, it is unclear whether the proposed electrical lead added to Mitsudou is arranged to detach only the single connector that Mitsudou breaks by balloon, or whether the lead is arranged to detach several weak connectors. As discussed below, if the rejection proposes to electrolytically detach a single connector, there is no reasonable expectation of success associated with the modified device. If the rejection proposes to detach all weak connectors, the rejection would change a principle of operation of the Mitsudou reference. In either case, a person of ordinary skill in the art would not have been motivated to modify Mitsudou as proposed by the Examiner.

Detachment of Single Connector

If the Examiner proposes to electrolytically detach a single Mitsudou weak connector, or a small number of weak connectors (e.g. two), the rejection suffers from an issue of preselection of the weak connector that is intended to break. The Examiner argues that the modification of Mitsudou "would enable disengagement of the disengagable connectors at desired locations directly with electrical leads." See Final Office Action at page 3. The "desired locations" language in the Examiner's statement suggest that not all of the weak connectors will be electrolytically detached, but only certain pre-selected weak connectors. However, the design of the Mitsudou stent intentionally avoids the preselection issue.

Mitsudou provides several weak connectors disposed along the length of the stent

because, at the time of manufacture, the final placement of any given weak connector with respect to the side branch vessel is unknown. Thus, many weak connectors are provided in any location that could potentially be positioned over the branch vessel, and the only weak connector that is eventually broken is the one that happens to be positioned over the branch vessel.

If the Examiner proposes to preselect a weak connector for electrolytic detachment, the resulting device would require precise placement because the preselected weak connector must be placed over the branch vessel. This would require precise longitudinal and rotational placement at the target site, whereas the original Mitsudou does not require such precise placement.

Mitsudou does not provide any mechanism for specific longitudinal and rotational placement of the stent at a target site, and the rejection does not propose to add any such placement features. The modified stent proposed by the Examiner could not be properly placed within a vessel at a bifurcation. Therefore, the modification would render the device unusable for its intended purpose.

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Detachment of Several Connectors

Mitsudou includes multiple weak connections 4 between two given annular members 2b, and the rejection proposes to break multiple weak connections electrolytically; however, the Examiner's proposal to disengage several of the weak connectors stems only from Applicants' disclosure.

The only reason that the weak connector of Mitsudou is broken is to provide an enlarged side branch opening. Mitsudou provides many weak connectors distributed throughout the midsection of the stent. See e.g. column 5, lines 12-15. A person of ordinary skill in the art would recognize that the vast majority (e.g. all but one) of the weak connectors are intended to stay connected, and that only a single weak connector in the area of the side branch opening is broken, if necessary.

In order to meet the limitations of claim 1, the rejection must propose to

electrolytically disengage all of the Mitsudou weak connectors between a given "first band" and "second band;" however, there is no prior art motivation to do so. Mitsudou's intention is for the weak connectors to generally stay connected.

Mitsudou does not disclose or suggest breaking every weak connector between a given "first band" and "second band," and a person of ordinary skill in the art would not have been motivated to do so. The rejection does not articulate any reason as to why a person of ordinary skill in the art would have been motivated to break all of the weak connections.

Mitsudou's purpose is to allow for selectively breaking a connector in the region of a side branch opening while leaving the remaining connectors intact. The proposed modification to break all of the weak connectors amounts to a change in a principle of operation of the reference.

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. See In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

The concept of breaking all of the weaker connector struts between a first band and a second band, while leaving the bands connected by a permanent connector strut, has been gleaned from Applicant's disclosure using impermissible hindsight.

3. The Applied References do not Disclose or Suggest Each Limitation of the Rejected Claims

Permanent Connector Strut

Independent claim 1 recites, "the first serpentine band connected to the second serpentine band by at least one *permanent connector strut*...each remaining valley of the first serpentine band connected to a peak of the second serpentine band by a disengagable connector strut" (emphasis added).

Independent claim 2 recites, "a first serpentine band connected to a second serpentine band by at least one *permanent connector strut*...the first serpentine band connected to the second serpentine band by at least one disengagable connector strut" (emphasis added).

Independent claim 35 recites, "each *permanent connector strut* connecting a valley of the first serpentine band to a peak of the second serpentine band, the plurality of disengagable connector struts connecting the remaining valleys of the first serpentine band to the remaining peaks of the second serpentine band" (emphasis added).

Thus, independent claims 1, 2 and 35 each require a permanent connector strut to connect between serpentine bands.

Applicants' Figure 1, an excerpt from which is provided below, shows an example embodiment of a permanent connector strut 20. The specification discusses first and second ends 22, 24 of a permanent connector strut 20. See e.g. page 6, lines 6-10.

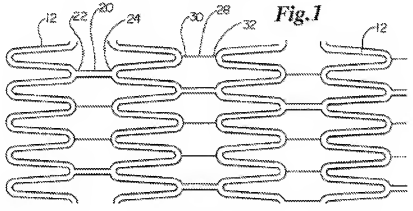


Fig.1

An obviousness rejection requires a suggestion of all limitations in a claim. See *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

Mitsudou does not disclose or suggest a "permanent connector strut" that connects between two bands that are also connected by disengagable connector strut(s), as required by the pending independent claims.

Citing Mitsudou Figure 21, the Examiner asserts, "Mitsudou discloses…at least one permanent connector (81) extending from a valley…." See Final Office Action at page 3. Thus, the rejection does not assert that Mitsudou teaches a "connector strut," but merely that Mitsudou has connections. An excerpt from Figure 21 is provided below.

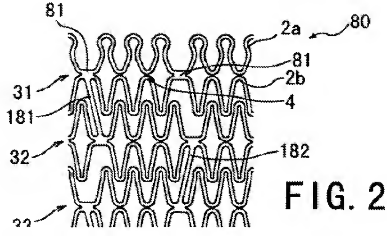


FIG. 21

Mitsudou describes the connection 81 as an integral or fused portion between the annular members 2a, 2b. Specifically, Mitsudou teaches "an integral portion (fused portion) 81 consisting of the valley of the first wavy annular member 2a and the mountain of the second wavy annular member 2b integrated (fused) therewith" and "The mountain of the second wavy annular member 2b and the valley of the first wavy annular member 2a are integral with each other partly through the integral portion (fused portion) 81." See column 11, lines 26-29 and column 12, lines 2-4. Thus, the connection 81 is a direct connection between the annular members, and not a connector strut.

The annular elements 2a, 2b that are connected by short connection portions 4 are not also connected by a permanent connector strut, as required by the rejected claims.

Although Mitsudou does show "joining portions 181" that could be considered connector struts, the annular elements that are connected by a joining portion 181 are not also connected by any weak connection portions 4. Thus, Mitsudou does not disclose or suggest two serpentine bands that are connected by a permanent connector strut and a disengagable connector strut, as required by the rejected claims. Acosta does not disclose or suggest a stent that meets these limitations. Therefore, the applied references do not disclose or suggest each limitation recited in the rejected claims.

Even if an electrode were provided for the Mitsudou stent, the resulting device would not meet the limitations of the rejected claims because the Mitsudou stent pattern does not meet the pattern requirements recited in the rejected claims. Therefore, the Examiner has not presented a *prima facie* case of obviousness against rejected independent claims 1, 2 or 35.

The remaining claims rejected under 35 USC § 103 are dependent claims that depend from one of independent claims 1, 2 or 35. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants request that the Board reverse all of the rejections asserted by the Examiner under 35 USC § 103 over Mitsudou in view of Acosta.

Higher Corrosion Potential

Independent claim 2 recites, "wherein at least a portion of said at least one disengagable connector strut is made from a material having a higher corrosion potential than a material used to form said serpentine bands."

The applied references do not discuss corrosion potential or teach forming a connector from a material having a higher corrosion potential than a material used to form other portions of the stent.

The Examiner makes the following assertion in the Final Office Action at page 3:

> Acosta teaches coupling an electrical lead to the disengagable struts to induce electrolytic detachment of the struts having reduced thickness portions (for example, see Figure 7) and inherently higher corrosion potential than the rest of the device (otherwise the entire device would corrode simultaneously destroying the device)

The reasoning behind the Examiner's statement that the Acosta connectors inherently have a higher corrosion potential is not understood. Acosta does not discuss corrosion potential. A person of ordinary skill in the art would recognize that it is not necessary for an electrolytically disengagable connector to be made from a different material than permanently engaged portions of the same stent.[1] Therefore, the Acosta device does not inherently require coupling portions that have a higher corrosion potential.

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1 For example, Applicants teach an embodiment where the disengageable connector strut acts as a fuse and melts. See page 9, lines 8-14. A person of ordinary skill in the art would recognize that such disengageable connector strut can be made from the same material as the connected serpentine bands.

The applied references do not disclose or suggest differential corrosion potential as recited in claim 2.

Further, the rejection does not propose to modify the Mitsudou weak connectors by substituting connectors from Acosta, so even if the Examiner's assertion were true, the rejection does not propose to reach the stent defined by claim 2. Applicants request that the Board reverse the Examiner's rejection of claim 2.

4. Dependent Claims Argued Separately

Dependent Claim 4

Claim 4 recites, "wherein said electrical lead is attached directly to at least one disengagable connector strut." Claim 4 requires more than merely an electrical (e.g. conductivity) connection between the electrical lead and the disengagable connector strut, and requires a direct physical connection.

Neither Mitsudou nor Acosta teach connecting an electrical lead directly to a frangible link. Acosta's teaching is limited to a general statement that, in some embodiments, the detachment mechanism could be electrolytic.

Thus, the applied references do not teach an electrical lead is attached directly to a disengagable connector strut as required by claim 4. Applicants request that the Board reverse the rejection of claim 4.

Dependent Claim 5

Claim 5 recites, "wherein said electrical lead is attached directly to each of the disengagable connector struts."

Neither Mitsudou nor Acosta teach connecting an electrical lead directly to a plurality of disengagable connector struts. Thus, the applied references do not teach each limitation of claim 5. Applicants request that the Board reverse the rejection of claim 5.

Dependent Claim 6

Claim 6 recites, "a second electrical lead, wherein each electrical lead connects to at least one disengagable connector strut."

Neither Mitsudou nor Acosta teach using multiple electrical leads. Thus, the applied references do not disclose or suggest each limitation of claim 6, and Applicants request that the Board reverse the rejection of claim 6.

Dependent Claim 8

Claim 8 recites, "wherein the stent self-expands to an intermediate deployment diameter, the stent being restrained from further expansion by at least one disengagable connector strut."

The applied references do not disclose or suggest a stent in accordance with claim 8. The Examiner does not address the limitations of this claim and has not proposed any modification to Mitsudou that would result in a stent that meets the limitations of this claim. Applicants request that the Board reverse the rejection of claim 8.

Dependent Claim 9

Claim 9 depends from claim 8 and recites, "wherein the stent self-expands to a full deployment diameter upon disengagement of said at least one disengagable connector strut."

The applied references do not disclose or suggest a stent in accordance with claim 9. The Examiner does not address the limitations of this claim and has not proposed any modification to Mitsudou that would result in a stent that meets the limitations of this claim. Applicants request that the Board reverse the rejection of claim 9.

Dependent Claim 12

Claim 12 recites, "wherein said at least one disengagable connector strut is connected to a serpentine band at a necked portion."

The applied references do not teach connection to a serpentine band at a necked portion. The Examiner makes the following assertion in the Final Office Action at page 4:

Since one having ordinary skill in the art could have connected the disengagable struts to the bands at the necked portion of the disengagable struts and the applicant has not stated any benefit of doing so, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the disengagable struts to the bands at the necked portion of the disengagable struts as a matter of design choice.

The Examiner has not provided any prior art teaching that the location of a necked portion of a disengageble connector can be arbitrarily moved to any location. The Examiner has not provided any motivation to arrange a necked portion as required by claim 12. The Examiner asserts that Acosta teaches a necked portion, but does not propose to modify any weak connector of Mitsudou to include a necked portion. Therefore, the Examienr has not presented a *prima facie* case of obviousness against claim 1.

Further, the benefit of a necked portion arranged as recited in claim 12 is that the disconnection location is at the connection between the disengagable connector strut and the serpentine band. Thus, the serpentine band will not have any portion of the disengagable connector strut attached to it after disengagement of the disengagable connector strut.

Applicants request that the Board reverse the rejection of claim 12.

Dependent Claim 37

Claim 37 recites, "wherein a portion of each cell is defined by a portion of a permanent connector strut after disengagement of said disengagable connector struts."

Mitsudou does not disclose or suggest connector struts that connect between annular elements that are also connected by weak connections 4. The connections 81 that the Examiner characterizes as "permanent connector struts" are not struts, but direct connections. This issue is discussed above in greater detail in pages 15-18.

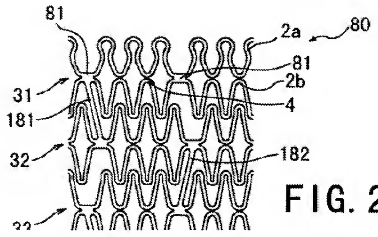

FIG. 21

Mitsudou describes the connection 81 as an integral or fused portion between the annular members 2a, 2b. See e.g. column 11, lines 26-29, column 12, lines 2-4 and Figure 21, provided above.

Even if all of the weak connectors were broken, the cell remaining between the two annular elements 2a, 2b would not be "defined by a portion of a permanent connector strut," as recited in claim 36. The device proposed by the Examiner would not meet the limitations of claim 37. Therefore, the Examiner has not presented a *prima facie* case of obviousness against claim 37.

Applicants request that the Board reverse the rejection of claim 37.

Dependent Claim 57

Claim 57 recites, "wherein at least a portion of a disengagable connector strut is made from a material having a higher corrosion potential than a material used to form said at least one permanent connector strut."

The applied references do not discuss corrosion potential or teach forming a connector from a material having a higher corrosion potential than a material used to form other portions of the stent. The Examiner does not propose to modify Mitsudou in a way that would result in these limitations. This issue is discussed in greater detail above with respect to independent claim 2 – see pages 18-19.

The applied references do not disclose or suggest differential corrosion potential as recited in claim 57, and the Examiner has not presented a *prima facie* case of obviousness against

claim 57. Applicants request that the Board reverse the rejection of claim 57.

Argument Conclusion

Based on at least the foregoing arguments, Applicants respectfully assert that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the pending claims. Accordingly, Applicants respectfully request that the Board reverse all of the rejections asserted by the Examiner.

Respectfully submitted,

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(viii) Claims Appendix

1. A stent comprising an expandable framework and an electrical lead, the expandable framework comprising:

a plurality of serpentine bands including a first serpentine band and a second serpentine band, adjacent serpentine bands connected by connector struts, each serpentine band comprising alternating peaks and valleys connected by band struts, the connector struts including permanent connector struts and disengageble connector struts;

the first serpentine band connected to the second serpentine band by at least one permanent connector strut extending from a valley of the first serpentine band to a peak of the second serpentine band;

each remaining valley of the first serpentine band connected to a peak of the second serpentine band by a disengagable connector strut;

wherein said electrical lead extends from said expandable framework and is electrically coupled to the disengagable connector struts such that the disengagable connector struts disengage by electrolytic detachment.

2. A stent for implantation in a living body comprising:

a first serpentine band connected to a second serpentine band by at least one permanent connector strut;

the first serpentine band connected to the second serpentine band by at least one disengagable connector strut;

wherein at least a portion of said at least one disengagable connector strut is made from a material having a higher corrosion potential than a material used to form said serpentine bands.

4. The stent of claim 1, wherein said electrical lead is attached directly to at least one disengagable connector strut.

5. The stent of claim 1, wherein said electrical lead is attached directly to each of the disengagable connector struts.

6. The stent of claim 1, further comprising a second electrical lead, wherein each electrical lead connects to at least one disengagable connector strut.

7. The stent of claim 1, wherein the stent is at least partially self-expanding.

8. The stent of claim 7, wherein the stent self-expands to an intermediate deployment diameter, the stent being restrained from further expansion by at least one disengagable connector strut.

9. The stent of claim 8, wherein the stent self-expands to a full deployment diameter upon disengagement of said at least one disengagable connector strut.

10. The stent of claim 1, wherein at least one disengagable connector strut comprises a necked portion.

11. The stent of claim 10, wherein said disengagement occurs at said necked portion.

12. The stent of claim 10, wherein said at least one disengagable connector strut is connected to a serpentine band at a necked portion.

13. The stent of claim 1, wherein upon disengagement of said at least one disengagable connector strut, said at least one disengagable connector strut no longer transmits forces between said first and second serpentine bands.

14. The stent of claim 1, wherein said stent transitions from a closed cell design to an open cell design upon disengagement of said disengageble connector struts.

35. A stent comprising:

a cylindrical metal framework having a plurality of cells, said framework comprising a first serpentine band, a second serpentine band, at least one permanent connector strut and a plurality of disengageble connector struts, each serpentine band comprising alternating peaks and valleys connected by band struts, each permanent connector strut connecting a valley of the first serpentine band to a peak of the second serpentine band, the plurality of disengagable connector struts connecting the remaining valleys of the first serpentine band to the remaining peaks of the second serpentine band; wherein the number of cells decreases upon disengagement of said disengagable connector strut; and wherein the mass of the metal in the metal framework decreases upon disengagement of said disengagable connector strut.

36. The stent of claim 35, wherein cells on either side of a disengagable connector strut combine to form a single cell upon disengagement of said disengagable connector strut.

37. The stent of claim 36, wherein a portion of each cell is defined by a portion of a permanent connector strut after disengagement of said disengagable connector struts.

38. The stent of claim 35, wherein the stent is at least partially self-expanding.

55. The stent of claim 35, wherein the stent is constructed and arranged such that the disengagable connector strut disengages by electrolytic detachment.

56. The stent of claim 35, comprising an electrical lead that is electrically coupled to said disengagable connector struts.

57. The stent of claim 35, wherein at least a portion of a disengagable connector strut is made from a material having a higher corrosion potential than a material used to form said at least one permanent connector strut.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None